



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 28, 2020

Meghan Shoun
Regulatory Affairs Specialist
Spartan Chemical Company, Inc.
1110 Spartan Drive
Maumee, OH 43537

Subject: PRIA Label Amendment – Adding SARS CoV-2 Claims
Product Name: Tumult
EPA Registration Number: 5741-28
Application Date: 07/22/2020
Decision Number: 564840

Dear Ms. Shoun:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Accepted label

Front Panel Copy:

Tumult

[RTU Bleach Disinfectant]

[Multipurpose] [Broad spectrum] [Hospital] [Healthcare]

[Cleaner Disinfectant with Bleach] [Cleans, Disinfects, Deodorizes, Virucidal*]

[Bactericidal]

[RTU Handi Spray]

[Kills spores of Clostridium difficile on hard, non-porous surfaces.]

[Alternate brand name:]

Diffense

ACTIVE INGREDIENTS:

Sodium hypochlorite.....0.74%

INERT INGREDIENTS:99.26%

Total100.00%

ACCEPTED

10/28/2020

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 5741-28

[Available Chlorine 0.70%]

[7000 PPM [Parts Per Million] Available Chlorine]

EPA Reg. No. 5741-28

EPA Est. No. 5741-OH-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

See side [back] panel[s] for additional precautionary statements [and first aid]

SPARTAN CHEMICAL COMPANY, INC., 1110 Spartan Drive, Maumee, Ohio 43537
1-800-537-8990 /www.spartanchemical.com

NET CONTENTS:

(Note to EPA: Bracketed information is denoted as: (optional text), [optional text]. The term “this product” used throughout this document may be replaced with the marketed product brand name. The term “x” is a place holder for numerical digits. Punctuation and plural/singular word forms may be adjusted to allow for grammatical correctness.

(Note to EPA: the following statements are optional)

(Note to EPA: the following marketing claims are optional)

This product [product name] is a [broad spectrum] [multipurpose][hospital] [healthcare] cleaner disinfectant for use on hard, non-porous which can be used [including] [such as]: (Insert **Use Site** selection)[and other] (Insert **Use Site** selection).

[This product] [product name] may be used to clean and disinfect [hard nonporous surfaces] [such as] (Insert **Objects** selection) [,] [and] (Insert **Objects** selection).

[This product] [product name] can be used on hard, non-porous surfaces made of (Insert **Materials** selection]

- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2² [virus]
- [Effective against] [Disinfects] [Kills] [99.9%] SARS-CoV-2² virus, the cause of COVID-19
- Kills [Eliminates] 99.9% - SARS-Related Coronavirus 2² [SARS-CoV-2] [USA-WA1/2020] [causative agent of COVID-19] [the virus that causes COVID-19]
- Disinfects surfaces by killing [99.9%] SARS-Related Coronavirus 2² [SARS-CoV-2] [USA-WA1/2020] [in One step]
- Kills [99.9% of] SARS-CoV-2², which causes COVID-19
- [Kills] [Effective against] the virus that causes COVID-19^{1,2}
- (This Product)(Product Name) kills SARS-CoV-2² the Novel Coronavirus that causes COVID-19
- (This Product) (Product Name) kills SARS-CoV-2²
- (This Product) (Product Name) kills COVID-19^{1,2}
- (This Product) (Product Name) kills SARS Covid-19²
- (This Product) (Product Name) kills COVID-19^{1,2} Coronavirus
- (This Product) (Product Name) kills COVID-19^{1,2} Coronavirus in (just) (X seconds)
- (This Product) (Product Name) kills SARS Covid-19² in (just) (X seconds)
- (This Product) (Product Name) kills COVID-19^{1,2} in (just) (X seconds)
- (This Product) (Product Name) kills SARS-CoV-2² in (just) (X seconds)
- (This Product) (Product Name) kills SARS-CoV-2² the Novel Coronavirus that causes COVID-19 in (just) (X seconds)
- (This Product) (Product Name) has demonstrated effectiveness against (COVID-19 Coronavirus) (SARS Covid-19) (COVID-19) (SARS-CoV-2) (SARS-CoV-2 the Novel Coronavirus that causes COVID-19) on hard, nonporous surfaces.
- (This Product) (Product Name) kills (COVID-19 Coronavirus) (SARS Covid-19) (COVID-19) (SARS-CoV-2) (SARS-CoV-2 the Novel Coronavirus that causes COVID-19) in just one step(!)³ on hard, nonporous surfaces.
- (This Product) (Product Name) kills (COVID-19 Coronavirus) (SARS Covid-19) (COVID-19) (SARS-CoV-2) (SARS-CoV-2 the Novel Coronavirus that causes COVID-19) in one easy step(!)³ on hard, nonporous surfaces.

Note: This product may discolor or otherwise damage colored fabric, clothing, metal trim, electronic devices/components or other surfaces which could be harmed by sodium hypochlorite. Check manufacturer's cleaning and disinfection recommendations before use on equipment surfaces.

¹SARS-Related Coronavirus 2

²On hard, non-porous surfaces

³When used according to the disinfection directions.

Efficacy Table:

BACTERICIDAL ACTIVITY (BACTERIA): (Using approved AOAC test methods (under Good Laboratory Practices, [GLPs]), in the presence of 5% blood serum and a 30 second contact time, unless otherwise noted, (this product or product name) kills the following organisms on hard non-porous inanimate surfaces:)		
Organism	ATCC Number	Contact Time
Escherichia coli, extended beta-lactamase resistant (ESBL)	ATCC BAA-196	30 seconds
Acinetobacter baumannii	ATCC 19606	30 seconds
Staphylococcus aureus	ATCC 6538	60 seconds
Pseudomonas aeruginosa	ATCC 6538	60 seconds
Staphylococcus aureus, methicillin resistant (MSRA)	ATCC 33592	60 seconds
Bacteria Sporicidal Activity	ATCC Number	Contact Time
Clostridium difficile, spore form	ATCC 43598	8 minutes
*See Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores		
*Virucidal Activity	ATCC Number	Contact Time
Hepatitis A Virus	Strain HM-175	30 seconds
Hepatitis B Virus	Hepadnavirus Testing, Inc	30 seconds
Hepatitis C Virus (Bovine Viral Diarrhea Virus (BVDV))	Oregon C24v-genotype 1 Strain	30 seconds
Poliovirus Type 1	ATCC VR-1562, Strain Chat	30 seconds
Norovirus (Norwalk virus)		30 seconds
Feline Calicivirus	ATCC VR-782	30 seconds
Rotavirus	Strain WA	30 seconds
Influenza A [(H1N1)] Virus	ATCC VR-1469, Strain A/PR/8/34	30 seconds
HIV Type 1 (HIV-1)	Strain HTLV-III	30 seconds
Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).		
Kills Pandemic 2009 H1N1 influenza A virus.		
SARS-CoV-2	COVID-19 virus	30 seconds

List of Use Sites, hard, non-porous surfaces:

Covers Medical/ General / Veterinary / Food Processing / Hospitality and Lodging / Education)

Hospitals

Nursing homes

Healthcare (settings)(facilities)

Doctor's offices

Patient care (rooms)(areas)

Long term healthcare facilities

Acute healthcare facilities Hospice facilities

Surgery rooms

Operating rooms

Office(s)((building)(s))

Schools

Hotels

Athletic facilities

Recreational facilities

(Lodging)(Hospitality) establishments

Any public place with restroom facilities

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Veterinarian offices
Veterinary clinics
Kennels
Catteries
Animal ((hospital(s)) (facilities)
Animal care facilities
Pet care areas
Kitchens
Restaurants
Cafes
Cafeterias
Food processing facilities
Food preparation areas
Bars
Cruise ships
Jails
Prisons
Correction(al) Facilities

(List of **Objects:** Within Medical/ General / Veterinary / Food Processing / Hospitality and Lodging /
Education / Correctional Facilities Use Sites)

Bed railings
Bed frame
TV remote
Bedside table
Telephone
Chair arm
Exam(ination) (table(s))(room)
Blood pressure cuff
IV Pole
High touch surfaces
Critical touch points
Bedpans
Floors
Walls
Countertops
Tables
Table tops
Door knobs
Light switch
Waste receptacles
Trash can
Showers
Shower stalls
Shower handles
Shower head
Faucets

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Urinals (above waterline)
Toilets (above waterline)
Toilet fixtures
Toilet paper dispenser
Restroom dispenser
Sink fixture
Restroom fixtures
Cages
Crates
Veterinary surfaces
Food cases
Food trays
Food preparation surfaces
Food prep surfaces
Dish racks
High touch points
Reusable restraints
Exercise equipment
Shared work equipment

(List of **Materials:** Product may be used on objects made from these materials)

Hard plastics
Stainless steel
Laminated counter tops
Laminated table tops
Glazed ceramic tile
Sealed fiberglass
Glass Nonporous flooring material
Glazed porcelain

(General Claims)

See expiration date on bottle
Bactericidal
Disinfectant
Virucidal*

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

EMERGING VIRAL PATHOGENS:

Product Name – or - this product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

Product Name – or - this product meets the criteria to makes claims against certain emerging viral pathogens from the following viral category:

- Small, non-enveloped virus
- Large, non-enveloped virus
- Enveloped virus

For an emerging viral pathogen that is a/an:	...follow the direction for use for the following organisms on the label:
Enveloped virus	Feline Calicivirus Rotavirus
Large, non-enveloped virus	Feline Calicivirus Rotavirus
Small, non-enveloped virus	Feline Calicivirus Rotavirus

Tumult [product name] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard non-porous surfaces. Therefore this product [product name] can be used against **[name of emerging virus]** when used in accordance with the directions for use against Norovirus (Norwalk virus) and Feline Calicivirus on hard, non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

To Clean & Deodorize

Spray area with this product [product name] [product] until surface is completely wet. Wipe off with a clean damp cloth or sponge.

Quick One Minute Disinfection Action

For one-minute disinfectant activity in the presence of 5% organic soil:

1. Spray area with this product [product name] [product] until surface is completely wet.
2. Allow surface to remain visibly wet for one minute
3. Wipe off with a clean damp cloth or sponge.

Preliminary cleaning is required for visibly soiled areas.

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(**Note to EPA:** These statements to be used when food contact surfaces are included on the label)

Before using this product in food processing areas, all food products and packaging materials must be removed from the room or carefully protected. After use, all food contact surfaces must be thoroughly rinsed with potable water before reuse. Do not use this product to disinfect or clean utensils, glasses, dishes, or cookware.

Special Instructions for Cleaning Prior to Disinfection against Clostridium difficile spores:

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant product. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Disinfection Procedure: Spray area with [product name] [this product] [product] until surface is completely wet. Allow surface to remain visibly wet for 8 minutes. Wipe off with a clean damp cloth or sponge.

KILLS HIV-1, HBV, AND HCV ON PRE-CLEANED ENVIRONMENTAL

SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV, AND HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable impervious gloves, gowns, masks, and eye coverings.

CLEANING PROCEDURES: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

CONTACT TIME: Allow surface to remain wet for 30 seconds. For all other organisms, see directions for contact times.

DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

To Clean and Disinfect in Veterinary Applications:

Use to clean and disinfect hard nonporous surfaces such as floors, walls, counter tops, cages, crates, utensils, kennels, stables, catteries, feeding and watering equipment, etc. Remove all animals and feed from premises, vehicles, and enclosures. Remove all litter and manure from walls, floors and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering equipment. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with [this product] [product] [product name] and let stand for [one] [1] minute. Rinse all surfaces with potable water. Ventilate buildings and other closed spaces. Do not house animals or use equipment until treated surfaces have been allowed to dry. Thoroughly scrub all treated feeding and watering appliances with soap or detergent and rinse with potable water before reuse.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. If present, remove contact lenses after the first 5 minutes then continue rinsing eye. Call a poison control center or doctor for further treatment advice.

24 HOUR MEDICAL EMERGENCY NUMBER: 888-314-6171

Have the product container or label with you when calling a poison center or doctor, or going for treatment.

PHYSICAL OR CHEMICAL HAZARDS

Mixing or using this product with gross filth such as feces or urine, ammonia, acids, or other chemicals may release hazardous gases irritating to the eyes, lungs and mucous membranes.

(Note to EPA: The following text will be used on five gallon pails and larger containers only.)

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes streams ponds estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting agency has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

(Note to EPA: The following text will be used on five gallon pails or less.)

STORAGE AND DISPOSAL

Do not contaminate water food, or feed by storage or disposal.

Pesticide Storage: Store in a cool, dry area inaccessible to children.

Pesticide Disposal: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

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Container Disposal: Nonrefillable container. Do not reuse or refill container. Triple rinse as follows: Fill container ¼ full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

[QUESTIONS OR COMMENTS? Call (800) 537-8990]

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